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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,586	09/09/2004	Bum-Joon Kim	038779/28077	7698

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ALSTON & BIRD LLP  
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CHARLOTTE, NC 28280-4000

EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/500,586	<b>Applicant(s)</b> KIM ET AL.	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on Preliminary Amendment.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicants' Preliminary Amendment is acknowledged.
2. Claims 1-16 are pending and under consideration.

### Specification

3. The disclosure is objected to because of the following informalities:

Page 1, lines 5-7, if a claim for priority is being made, then the statement is to be amended to make the claim for priority; lines 13 and 15, "Mycobacterial" should be "mycobacterial"; line 17, "Mycobacterium" should be "*Mycobacterium*"; line 21, "mycobacterium" should be "*Mycobacterium*".

Page 2, lines 1, 2, and 22, "Mycobacterial" should be "mycobacterial"; lines 2-4, "M. tuberculosis" should be "*M. tuberculosis*", "M bovis" should be "*M. bovis*", "M. africanum" should be "*M. africanum*", "M. microti" should be "*M. microti*"; line 16, "Mycobacterium tuberculosis" should be "*Mycobacterium tuberculosis*"; lines 17 and 20, "causes" should be "cause"; line 22, "Mycobacterial" should be "mycobacterial".

Page 3, lines 7, 10, 16, "Mycobacteria" should be "mycobacteria"; lines 9, 17, and 22, "Mycobacterial" should be "mycobacterial".

Page 4, line 1, "Mycobacteria" should be "mycobacteria"; lines 2, 6, "Mycobacterial" should be "mycobacterial".

Page 8, line 5, "Figs. 7a to 7d" should be "Figs. 7A to 7D"; lines 16, 20, 21, "M. tuberculosis" should be "*M. tuberculosis*".

Page 10, line 4, "M. tuberculosis" should be "*M. tuberculosis*"; line 11, "M. leprae" should be "*M. leprae*"; line 14, "Tsukamurella" should be "*Tsukamurella*".

Page 12, line 2, "Mycobacterial" should be "mycobacterial".

Art Unit: 1645

Page 14, lines 14-15, "M. avium and M. intracellulare" should be "*M. avium* and *M. intracellulare*"; line 17, "M. kansasii and M. gastri" should be "*M. kansasii* and *M. gastr*"; line 20, "M. kansasii" should be "*M. kansasii*".

Page 15, line 2, "M. tuberculosis and M. lepre" should be "*M. tuberculosis* and *M. leprae*"; line 19, "comprising" should be "comprises".

Page 17, line 6, "M. tuberculosis" should be "*M. tuberculosis*"; line 15, "Mycobacterium" should be "*Mycobacterium*".

Page 22, line 2, "M. gordonae" should be "*M. gordonae*"; line 3, "M. tuberculosis" should be "*M. tuberculosis*".

Page 25, line 6, , "Figs. 7a to 7d" should be "Figs. 7A to 7D"; lines 9 and 10, "M. tuberculosis" should be "*M. tuberculosis*".

Page 26, lines 2, 4, "M. tuberculosis" should be "*M. tuberculosis*"; lines 13, 16, 17, 19, "M. avium" should be "*M. avium*"; lines 15, 17, 21, 22, "M. intracellulare" should be "*M. intracellulare*".

Page 27, line 1, "M. intracellulare" should be "*M. intracellulare*"; line 9, "Fig.7b" should be "Fig. 7B"; line 13, "M. avium" should be "*M. avium*", "M. kansasii" should be "*M. kansasii*"; line 15, "M. gastri" should be "*M. gastr*".

Page 28, lines 3-4, "M. gordonae, M. szulgai, M. marinum, and M. terrae" should be "*M. gordonae, M. szulgai, M. marinum, and M. terrae*"; lines 7, 22, "Fig. 7a" should be "Fig. 7A".

Page 29, line 4, "Fig. 7a" should be "Fig. 7A".

Page 30, line 23, "M. leprae" should be "*M. leprae*".

Appropriate correction is required.

Art Unit: 1645

### **Drawings**

4. M.P.E.P. §2422.02, third paragraph, recites that "the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings." Figure 1 contains sequences without the required sequence identifiers. Appropriate correction is required.

### **Claim Objections**

Claim 10 is objected to because of the following informalities: the names of bacterial should be in italics for uniformity with the other claims. Appropriate correction is required.

### **Claim Rejections - 35 USC § 112**

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a pair of primers for specifically amplifying an hsp 65 gene fragment of mycobacterial species comprising the nucleotide sequences as shown in SEQ ID NO:55 and SEQ ID NO:56.

It is unclear if: 1) the gene fragment comprises the nucleotide sequences as shown in SEQ ID NO:55 and SEQ ID NO:56, 2) each of the primers comprises both nucleotide sequences as shown in SEQ ID NO:55 and SEQ ID NO:56, 3) one primer comprises nucleotide sequence

Art Unit: 1645

SEQ ID NO:55 and the other primer comprises nucleotide sequence SEQ ID NO:56, or 4) if the primers, due to the use of the language "as shown in", consist of the entire sequence of SEQ ID NO:X or a subsequence of sequence SEQ ID NO:X.

Claims 8-15 depend from claim 1, but do not clarify the issues.

7. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a polynucleotide of an hsp 65 gene fragment wherein the fragment is amplified by using a pair of primers for specifically amplifying the hsp 65 gene fragment of mycobacterial species comprising the nucleotide sequences as shown in SEQ ID NO:55 and SEQ ID NO:56.

It is unclear if: 1) the gene fragment comprises the nucleotide sequences as shown in SEQ ID NO:55 and SEQ ID NO:56, 2) each of the primers comprises both nucleotide sequences as shown in SEQ ID NO:55 and SEQ ID NO:56, 3) one primer comprises nucleotide sequence SEQ ID NO:55 and the other primer comprises nucleotide sequence SEQ ID NO:56, or 4) if the primers, due to the use of the language "as shown in", consist of the entire sequence of SEQ ID NO:X or a subsequence of sequence SEQ ID NO:X.

8. Claims 3, 4, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a polynucleotide selected from the group consisting of polynucleotides as shown in SEQ ID NO:1 to SEQ ID NO:54, and polynucleotides complementary thereto.

Art Unit: 1645

Because of the language "as shown in", it is unclear if the claimed polynucleotide consists of the entire sequence of SEQ ID NO:X or a subsequence of sequence SEQ ID NO:X.

9. Claims 5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Because the claim does not identify any particular sequences, it is unclear what primers (and their identity/length) are to be utilized for the method. In addition, it is unclear what methodology is put forth by step 2, i.e., what is the analyzing procedure.

It is unclear how one identifies a particular species of mycobacteria using step 3 because the step does not require any specific species, only that the obtained nucleotide sequence be compared to "a" reference species. How does one identify the obtained polynucleotide species if, for instance, it is from *M. avium*, and the reference mycobacterial species fragment is from *M. xenop*?

10. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim depends from claim 5 and as such is indefinite for the same reasoning as put forth for the rejection of claim 5. In addition, claim 6 recites that "the primers comprise the polynucleotides as shown in SEQ ID NO:55 and SEQ ID NO:56". Because of the language "as shown in", it is unclear if the claimed polynucleotide consists of the entire sequence of SEQ ID NO:X or a subsequence of sequence SEQ ID NO:X.

Art Unit: 1645

11. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is to a probe selected from the group consisting of polynucleotides as shown in SEQ ID NO:1 to SEQ ID NO:54, and polynucleotides complementary thereto.

Because of the language "as shown in", it is unclear if the claimed polynucleotide consists of the entire sequence of SEQ ID NO:X or a subsequence of sequence SEQ ID NO:X.

### **Conclusion**

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

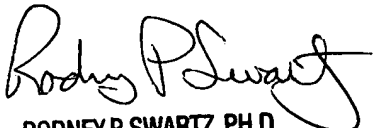
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Application/Control Number: 10/500,586

Page 8

Art Unit: 1645

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

January 5, 2007